

CLAIMS

1. A method of simultaneously detecting at least one Hepatitis C Virus (HCV) antigen and at least one HCV antibody in a test sample comprising the steps of:

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- a) contacting said test sample with: 1) at least one HCV viral antigen or portion thereof coated on a solid phase, for a time and under conditions sufficient for the formation of antibody/antigen complexes and 2) at least one antibody to HCV or portion thereof coated on said solid phase, for a time and under conditions sufficient for the formation of antigen/antibody complexes;
  - b) detecting said antibody/antigen complexes, presence of said complexes indicating presence of HCV antigen in said test sample; and
  - c) detecting said antigen/antibody complexes, presence of said complexes indicating presence of HCV antibody in said test sample.

2. The method of claim 1 wherein said at least one HCV antigen coated on the solid phase is selected from the group consisting of core antigen, NS3, NS4, NS5, and portions thereof.

3. The method of claim 2 wherein said at least one antibody coated on said solid phase is a monoclonal antibody selected from the group consisting of 13-959-270, 14-1269-281, 14-1287-252, 14-153-234, 14-153-462, 5 14-1705-225, 14-1708-269, 14-1708-403, 14-178-125, 14-188-104, 14-283-112, 14-635-225, 14-726-217, 14-886-216, 14-947-104, 14-945-218, 107-35-54, 110-81-17, 13-

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975-157, 14-1350-210, C11-3, C11-7, C11-10, C11-14 and  
C11-15.

4. The method of claim 3 wherein said at least  
5 one antibody coated on the solid phase is not reactive  
with said at least one antigen coated on the solid  
phase.

5. The method of claim 1 wherein said at least  
10 one antibody is a HCV anti-core monoclonal antibody and  
said at least one antigen is a recombinant HCV core  
protein.

6. The method of claim 5 wherein said  
15 recombinant core protein does not contain epitopes to  
which said anti-core monoclonal antibody binds.

7. The method of claim 1 wherein said solid phase  
is a microparticle.

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8. A method for simultaneously detecting the  
presence of at least one HCV antigen and at least one  
HCV antibody in a test sample comprising the steps of:

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a) contacting said test sample with: 1) at least  
one HCV viral antigen or portion thereof coated on a  
solid phase, for a time and under conditions sufficient  
for the formation of antibody/antigen complexes and 2)  
at least one HCV antibody or portion thereof coated on  
30 said solid phase, for a time and under conditions  
sufficient for the formation of antigen/antibody  
complexes;

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5 b) adding a conjugate to the resulting antibody/antigen complexes for a time and under conditions sufficient to allow said conjugate to bind to the bound antibody in (a) (1), wherein said conjugate comprises a second antibody attached to a chemiluminescent compound capable of generating a detectable signal and simultaneously adding a second conjugate to the resulting antigen/antibody complexes for a time and under conditions sufficient to allow  
10 said conjugate to bind to the bound antigen in (a) (2), wherein said conjugate comprises a third antibody attached to said chemiluminescent compound capable of generating a detectable signal; and

15 c) detecting said generated signal, presence of said signal indicating presence of at least one antigen in said test sample selected from the group consisting of HCV antigen and HCV antibody.

9. The method of claim 8 wherein said at least one HCV antigen coated on the solid phase is selected from the group consisting of core antigen, NS3, NS4, NS5, and portions thereof.

10. The method of claim 9 wherein said at least  
20 one antibody coated on said solid phase is a monoclonal antibody selected from the group consisting of 13-959-270, 14-1269-281, 14-1287-25, 14-153-234, 14-153-462, 14-1705-225, 14-1708-269, 14-1708-403, 14-178-125, 14-188-104, 14-283-112, 14-635-225, 14-726-217, 14-886-  
25 216, 14-947-104, 14-945-218, 13-975-157 and 14-1350-210, 107-35-54, 110-81-17, C11-3, C11-7, C11-10, C11-14 and C11-15.

11. The method of claim 10 wherein said at least one monoclonal antibody coated on the solid phase is not reactive with said at least one antigen coated on 5 the solid phase.

12. A kit comprising:  
a) a container containing at least one HCV antigen  
coated on a solid phase; and  
10 b) a container containing at least one HCV antibody coated on a solid phase.

13. A kit comprising:  
a container containing: 1) at least one HCV 15 antigen coated on a solid phase and 2) at least one HCV antibody, coated on said solid phase.

14. The kit of claim 12 or claim 13 further comprising at least one conjugate comprising a signal-  
20 generating compound attached.

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15. The kit of claim 14 wherein said signal-  
generating compound is acridinium.

25 16. A method of detecting at least one HCV antigen in a test sample comprising the steps of:

a) contacting said test sample with at least one HCV antibody coated on a solid phase, for a time 30 and under conditions sufficient for the formation of antibody/antigen complexes; and

b) detecting the presence of antibody/antigen complexes, presence of said complexes indicating presence of said at least one HCV antigen in said test sample.

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17. A method of detecting at least one HCV antigen in a test sample comprising the steps of:

a) contacting said test sample with at least 10 one HCV antibody coated on a solid phase, for a time and under conditions sufficient for the formation of antibody/antigen complexes;

b) adding a conjugate to the resulting antibody/antigen complexes for a time and under 15 conditions sufficient to allow said conjugate to bind to the bound at least one antibody, wherein said conjugate comprises a second antibody attached to a chemiluminescent compound capable of generating a detectable signal; and

c) detecting said signal generated by said 20 chemiluminescent compound, a signal generated by said chemiluminescent compound indicating the presence of at least one HCV antigen in said test sample.

25 18. A recombinant protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:12, SEQ ID NO:16, and conservative amino acid substitutions thereof.

30 19. A recombinant protein comprising an amino acid

sequence encoded by a nucleotide sequence selected from the group consisting of, for example, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:11 and SEQ ID NO:15.

5        20. A vector or construct comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:11 and SEQ ID NO:15.

10      21. A host cell comprising said vector or construct of claim 20.

15      22. An immunoassay which simultaneously detects at least one HCV antigen and at least one HCV antibody in a test sample.

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